In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P., Plaintiffs, -against- AMNEAL PHARMACEUTICALS, LLC, Defendant.	13 Civ. 3372 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS USA, INC., Defendant.	13 Civ. 4606 (SHS) OPINION & ORDER

SIDNEY H. STEIN, U.S. District Judge.

This Hatch-Waxman Act litigation is the latest in a series of related actions concerning the brand-name drug OxyContin, which is manufactured and sold by plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue"). Defendants—Amneal Pharmaceuticals, LLC and Teva Pharmaceuticals USA, Inc.—have filed Abbreviated New Drug Applications ("ANDAs") seeking to sell generic versions of OxyContin. Plaintiffs contend that defendants' ANDAs infringe two patents that claim the OxyContin formulation currently sold in the United States. Purdue, as well as plaintiff Grünenthal GmbH (collectively with Purdue, "plaintiffs"), developed these patents to address the problem of widespread abuse of original OxyContin by users who snorted or injected crushed or dissolved

tablets.[1] These patents, along with others the Court has previously considered, are embodied in Purdue's "Reformulated OxyContin," the only form of the drug that Purdue now sells in the United States.

The two patents before the Court are Purdue's U.S. Patent No. 8,337,888 ("'888 Patent") (Ex. 1 to Decl. of Rebecca R. Hermes dated Jan. 15, 2014 ("Hermes Decl.")) and Grünenthal's U.S. Patent No. 8,309,060 ("'060 Patent") (Ex. 2 to Hermes Decl.). On March 7, 2014, the Court held a *Markman* hearing to construe the disputed portions of the claims at issue in these two patents. This Opinion and Order is the result.

I. BACKGROUND

The Court assumes familiarity with Purdue's development of Reformulated OxyContin, as detailed in the Court's August 23, 2013 Claim Construction Opinion and Order, 965 F. Supp. 2d 420 (S.D.N.Y. 2013), and its January 14, 2014 Findings of Fact and Conclusions of Law, No. 04 Md. 1603, 2014 WL 128013 (S.D.N.Y. Jan. 14, 2014).

The '888 Patent is a product of inventions Purdue made in the early 2000s. *See* '888 Patent at [60], [63] (listing related application data); (Pls.' Opening Br. 1.) After reports of abuse of original OxyContin emerged, scientists at Purdue began exploring how to deter snorting and injection, the most common methods of abuse. (Pls.' Opening Br. 6; Ex. 3 to Hermes Decl., at 24, 111; Ex. 4 to Hermes Decl., at 24–25). The '888 Patent discloses and claims a dosage form that utilizes a gelling agent to deter abuse by snorting and injection. '888 Patent at 2:64–3:24, 7:4–12, 40:25–29. The patent claims polyethylene oxide ("PEO") as an acceptable gelling agent. *Id.* at 40:25. Purdue scientists determined that when a dosage form containing the gelling agent was combined with a small quantity of aqueous liquid, the mixture formed a gel that was difficult to inject from a syringe. *Id.* at 3:5–19. Moreover, when the dosage form was crushed and then snorted, it became gel-like through contact with moisture in the nasal passages, reducing the amount of the drug that could be absorbed nasally. *Id.* at 3:25–30. The '888 Patent issued in December 2012. *Id.* at [45].

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[1] Crushing the tablet defeats its controlled-release mechanism. '888 Patent at 1:26–29. In addition, parenteral (non-oral) administration typically results in greater potency than oral administration. *Id.* at 1:18–20. OxyContin abusers achieved a "high" by crushing the tablets and then injecting or snorting the powder. *See id.* at 1:20–25, 7:4–12.

The '060 Patent is a divisional application of the application that issued as Grünenthal's U.S. Patent No. 8,114,383 ("the '383 Patent").[2] '060 Patent at [62]. Like the '383 patent, the '060 Patent discloses and claims "a thermoformed dosage form" that resists crushing by virtue of its 500 Newton breaking strength. *Compare* '060 Patent at 2:17–32, 21:13–14, *with* '383 Patent at 2:7–13, 21:1–14. The '060 Patent names several polymers, including PEO, as suitable hardening agents. '060 Patent at 5:54–63. Unlike the '383 Patent, however, the '060 Patent includes claims that call for additional protection against abuse should an abuser nonetheless manage to crush the dosage form. *Id.* at 6:24–34, 21:37–51. This further protection is achieved through the addition of irritants, bittering agents, dyes, emetics, and/or gelling agents to the dosage form, which make inappropriate administration of the drug difficult or unpleasant. *Id.* at 6:24–34, 8:28–38, 12:1–7, 21:37–51.

II. LEGAL STANDARD

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks and citations omitted). "Generally, a claim term is given the ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of invention." *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, No. 2013-1201, 2014 WL 1855416, at *8 (Fed. Cir. May 9, 2014).

The Federal Circuit has stressed "the importance of intrinsic evidence" in discerning the ordinary and customary meaning of claims. *Phillips*, 415 F.3d at 1317. The analysis "must begin and remain centered on the claim language itself." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) (internal quotation marks and alterations omitted). "Claims, however, must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). That context includes the specification, which "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal

[2] The Court found the '383 Patent invalid as anticipated and obvious in its January 2014 Findings of Fact and Conclusions of Law. *In re OxyContin Antitrust Litig.*, 2014 WL 128013 at *86, *90.

quotation marks and citation omitted). "The prosecution history too, as part of the intrinsic record, has an important role in claim construction by supplying context to the claim language." *Aventis*, 715 F.3d at 1373.

Courts may also look to extrinsic evidence—"all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (internal quotation marks and citations omitted). Such evidence, however, may not be used "to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1324. "Ultimately, the construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1363 (Fed. Cir. 2014) (internal quotation marks, citations, and alterations omitted).

With these legal principles in mind, the Court addresses the disputed claims.

III. CONSTRUCTION OF THE DISPUTED CLAIMS IN THE '888 PATENT

Of the '888 Patent's 24 claims, Purdue asserts all but claim 10 against defendants.[3] (Pls.' Opening Br. 10.) The parties dispute the meaning of certain terms in independent claim 1 and dependent claims 23 and 24. The disputed claims read:

> 1. A controlled release oral dosage form comprising:
> . . .
> a gelling agent comprising polyethylene oxide in an effective amount to impart a viscosity of at least about 10 cP when the dosage form is subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous liquid;
> . . .
>
> 23. The controlled release oral dosage form of any of claims 2, 4, 5, 6 and 7, wherein the viscosity is obtained when the dosage form is subjected to tampering by crushing and dissolution in the aqueous liquid.
>
> 24. The controlled release oral dosage form of any of claims 2, 4, 5, 6 and 7, wherein the viscosity is obtained when the dosage form is

[3] Purdue asserts claims 8 and 9 against Teva alone. (Pls.' Opening Br. 10 n.6.)

subjected to tampering by dissolution in the aqueous liquid with heating greater than 45° C.

'888 Patent at 40:22, 40:25–29, 42:10–17. The Court separately addresses each of the disputed terms below.

A. Claim 1

Claim 1 provides that the dosage form obtains "a viscosity of at least about 10 cP when [it] is subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous liquid." '888 Patent at 40:26–29. The parties refer to this claim language as the "viscosity test." (Hr'g Tr. 51, 54.) Purdue submits only the term "tampering" for construction, urging the Court to give it the same meaning as "tampered dosage form," which the patentees defined in the patent specification at 4:15–25. (Pls.' Opening Br. 11.) Defendants specifically "do not separately address this term" and decline to propose a construction. (Defs.' Opening Br. 7 n.6.) They instead submit the viscosity test in its entirety for the Court's consideration. They do not suggest a particular construction, however, arguing that the viscosity test is indefinite. (Defs.' Opening Br. 7 & n.6, 8.)

1. The Court declines to rule on the issue of indefiniteness of the viscosity test prior to trial

Defendants admit that the specification provides a definition of "tampering" (through its definition of "tampered dosage form"), but argue that the viscosity test of claim 1 is indefinite when read in its entirety. (Hr'g Tr. 53–54, 62; Defs.' Opening Br. 7–8). Defendants contend that the patent provides no guidance on the various factors that they argue impact viscosity, viz., the particle size of the dosage form; the type of aqueous liquid in which it is dissolved; how long it remains in the aqueous liquid; whether the dosage form and aqueous liquid are stirred; and the temperature, shear rate, and type of equipment used to measure viscosity. (Defs.' Opening Br. 8–13; Hr'g Tr. 54–56, 63–64.)

The Court refrains from ruling on the issue of indefiniteness prior to trial. A full record will better enable the Court to determine whether the various factors that defendants have identified render the viscosity test insolubly ambiguous. *See In re OxyContin Antitrust Litig.*, 965 F. Supp. 2d 420, 432 n.3 (S.D.N.Y. 2013); *Alcon Research, Ltd. v. Barr Labs. Inc.*, No. 09-CV-0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011) ("We find that the

indefiniteness issue is best decided at trial and defer consideration on it until that time."). The Court therefore proceeds to construe the disputed claim language.

2. "Tampering by dissolution" means dissolution of the dosage form that is optionally accompanied by additional means of tampering

As noted above, Purdue submits the term "tampering" for construction, asking the Court to construe it the same way the patentees defined "tampered dosage form." (Pls.' Opening Br. 11; Hr'g Tr. 47.) Purdue overlooks the fact that claim 1 does not utilize the solitary term "tampering," but rather refers to "tampering by dissolution." '888 Patent at 40:27–28. Simply adopting the patentees' definition of "tampered dosage form," therefore, would not resolve the issues of construction that claim 1 presents.

Still, the specification's definition of "tampered dosage form" sheds light on the meaning of "tampering by dissolution." It provides:

> The term "tampered dosage form" is defined for purposes of the present invention to mean that the dosage form has been manipulated by mechanical, thermal, and/or chemical means which changes the physical properties of the dosage form, e.g., to liberate the opioid agonist for immediate release if it is in sustained release form, or to make the opioid agonist available for inappropriate use such as administration by an alternate route, e.g., parenterally. The tampering can be, e.g., by means of crushing, shearing, grinding, chewing, dissolution in a solvent, heating, (e.g., greater than about 45° C.), or any combination thereof.

'888 Patent at 4:15–25. Defendants agree that this language explains what the patentees meant by tampering. (Hr'g Tr. 54, 62.) The issue then becomes how to construe the term "tampering by dissolution" that is found in claim 1.

Importantly, no party argues that "tampering by dissolution" means tampering *only* by dissolution, to the exclusion of other means of tampering described in the specification. (*See* Pls.' Opening Br. 12; Defs.' Opening Br. 8; Decl. of Fernando J. Muzzio dated Jan. 15, 2014 ("Muzzio Decl.") ¶ 30.) Both parties' expert witnesses noted that a person of

ordinary skill in the art understands that additional manipulation of the dosage form during or prior to dissolution—such as by heating, crushing, or grinding—tends to facilitate the process of dissolution. (Decl. of Martyn C. Davies dated Feb. 14, 2014 ("Davies Decl.") ¶ 39; *see* Muzzio Decl. ¶ 32.)

Moreover, the specification clarifies that although claim 1 specifically requires dissolution, other forms of tampering may also occur. The specification twice refers to a dosage form that is "tampered with" and then dissolved. '888 Patent at 7:21–24, 7:28–31. It further provides:

> In certain preferred embodiments, when the dosage form is tampered with and exposed to a small amount (e.g., less than about 10 ml) of an aqueous liquid (e.g., water), the dosage form will be unsuitable for injection and/or inhalation. Upon the addition of the aqueous liquid, the tampered dosage form preferably becomes thick and viscous, rendering it unsuitable for injection.

'888 Patent at 3:5–11. By disclosing a preferred embodiment calling for tampering *followed by* exposure to an aqueous liquid, the patentees signaled that the phrase "tampering by dissolution" encompasses more than just dissolution. Indeed, if claim 1—from which all the other claims depend—were read to exclude other forms of tampering, the preferred embodiment would not fall within the patent. Such constructions are strongly disfavored and require "highly persuasive evidentiary support," which the '888 specification lacks. *SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013) (internal quotation marks and citation omitted).

For these reasons, the Court construes "tampering by dissolution" to mean dissolution of the dosage form that is optionally accompanied by the methods of tampering described in the specification's definition of "tampered dosage form."

3. "Aqueous liquid" means "aqueous liquid"

Purdue urges the Court to specifically identify water as an example of the "aqueous liquid" referenced in the viscosity test. (Pls.' Opening Br. 13 (proposing the language "e.g., water").) The parties agree that water is an example of an aqueous liquid and that the term "aqueous liquid" in claim 1 is not limited to water. (Hr'g Tr. 49, 54.) Nor is it disputed that a person of ordinary skill in the art would understand that water is an example of

an aqueous liquid. (Muzzio Decl. ¶ 33; Davies Decl. ¶ 43.) Consequently, Purdue's proposed clarification of "aqueous liquid" is unnecessary because there is no actual dispute over that term. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (stating that "only those terms need be construed that are in controversy").

* * *

For these reasons, the Court construes claim 1 of the '888 Patent to read as follows:

> 1. A controlled release oral dosage form comprising:
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> . . .
>
> a gelling agent comprising polyethylene oxide in an effective amount to impart a viscosity of at least about 10 cP when the dosage form is subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous liquid; such dissolution having optionally been accompanied by tampering with the dosage form through mechanical, thermal, and/or chemical means of manipulation which changes the physical properties of the dosage form, e.g., to liberate the opioid agonist for immediate release if it is in sustained release form, or to make the opioid agonist available for inappropriate use such as administration by an alternate route, e.g. parenterally; the tampering can be, e.g., by means of crushing, shearing, grinding, chewing, dissolution in a solvent, heating (e.g., greater than about 45° C.), or any combination thereof;
>
> . . .

B. Claims 23 and 24

Due to their similarity, the Court addresses claims 23 and 24 together. Both claims recite a "dosage form of any of claims 2, 4, 5, 6, and 7." '888 Patent at 42:10–11, 42:14–15. Claims 23 and 24 exhibit a "multiple dependent claim" structure—they "refer[] back in the alternative to more than one preceding independent or dependent claim." MPEP § 608.01(n) (9th ed., Mar. 2014). Claims 2, 4, 5, 6, and 7, in turn, depend from claim 1. '888 Patent at 40:33, 40:41, 40:45, 40:47, 40:51. Therefore, claims 23 and 24 contain all the limitations of claim 1, as well as any further limitations imposed by whichever of claims 2, 4, 5, 6, or 7 is being considered. *See* 35 U.S.C. § 112(e) ("A multiple dependent claim shall be construed to

incorporate by reference all the limitations of the particular claim in relation to which it is being considered.").

Claims 23 and 24, as the parties agree, limit the claims from which they depend by prescribing a specific method of tampering. (*See* Pls.' Opening Br. 14–15; Defs.' Opening Br. 14.) Claim 23 provides that "the viscosity is obtained when the dosage form is subjected to tampering by crushing and dissolution in the aqueous liquid." '888 Patent at 42:11–13. Similarly, claim 24 states that "the viscosity is obtained when the dosage form is subjected to tampering by dissolution in the aqueous liquid with heating greater than 45° C." *Id.* at 42:15–17.

Defendants argue that claims 23 and 24 are indefinite for the same reason as claim 1: their lack of guidance on the variables that, according to defendants, influence viscosity. (Defs.' Opening Br. 14.) However, defendants propose no construction for the Court to consider. Again, the Court defers ruling on the issue of indefiniteness.

With respect to claim 23, Purdue asks the Court to construe the disputed language to mean "wherein the viscosity of at least about 10 cP is obtained when the dosage form is subjected to manipulation by tampering that includes crushing and dissolution in from about 0.5 to about 10 ml of an aqueous liquid, e.g. water." (Pls.' Opening Br. 14.) Its proposed construction of claim 24 is very similar: "wherein the viscosity of at least about 10 cP is obtained when the dosage form is subjected to manipulation by tampering that includes dissolution in from about 0.5 to about 10 ml of an aqueous liquid, e.g. water, with heating greater than 45° C." (*Id.* 15.) In essence, Purdue attempts to clarify the required level of viscosity and amount of aqueous liquid by referring back to the language of claim 1, from which claims 23 and 24 (by way of claims 2, 4, 5, 6, and 7) depend.

The Court rejects Purdue's constructions because they create the potential for misinterpretation of the claim language. Were the Court to adopt Purdue's proposed language, claims 23 and 24 would appear to disregard the limitations of claims 6 and 7. *See* 35 U.S.C. § 112(e); *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (noting that "independent claims are presumed to have broader scope than their dependents"); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 1000 (Fed. Cir. 1995) (en banc) (noting that "a dependent claim includes all of the limitations of the independent claim"), *aff'd*, 517 U.S. 370 (1996). Specifically, claim 6 provides that the dosage form is dissolved in about 1

to about 3 ml of an aqueous liquid, '888 Patent at 40:48–50, a range of volume that is more limited than Purdue's suggested construction. Similarly, claim 7 requires a viscosity of "at least about 60 cP," *id.* at 40:52, six times greater than Purdue's suggestion of 10 cP. Although the presumption that dependent claims are narrower than the claims from which they depend is not irrefutable, *see Acumed*, 483 F.3d at 806, there is no evidence to suggest that the patentees disavowed that general rule. Consequently, even if adopting Purdue's constructions would not technically override the limitations of claims 6 and 7, it would create unnecessary confusion because Purdue's proposed viscosity and volume limitations are meaningless when read in light of the dissimilar requirements of claims 6 and 7.

To avoid the problems posed by Purdue's constructions, the Court will construe claims 23 and 24 to refer to the "requisite viscosity" and the "specified volume of aqueous liquid," rather than utilizing the particular ranges of viscosity and volume that Purdue suggests. Because claims 23 and 24 do not specify the necessary viscosity and volume of aqueous liquid but do refer back to other claims, a person of ordinary skill in the art would know to look to those claims to ascertain that information. (*See* Davies Decl. ¶ 44.) In other words, a person of skill in the art would interpret claims 23 and 24 to require about 0.5 to about 10 ml of aqueous liquid and a viscosity of at least about 10 cP, if they depend from claims 2, 4, or 5; about 1 to about 3 ml of aqueous liquid and viscosity of at least about 10 cP, if they depend from claim 6; and about 0.5 to about 10 ml of aqueous liquid and a viscosity of at least about 60 cP, if they depend from claim 7.

The Court does agree with Purdue, however, that claims 23 and 24 should be construed to allow methods of tampering besides those specified in the claims. (*See* Pls.' Opening Br. 14–15.) Defendants do not argue to the contrary. The specification does not shed much light on the meaning of claims 23 and 24. Both claims require dissolution, however, and a person of ordinary skill in the art understands that the methods of tampering described in the specification tend to facilitate dissolution. (Davies Decl. ¶ 39; *see* Muzzio Decl. ¶ 32.) Moreover, the claims' internal structure and use of the phrase "tampering by" are very similar to claim 1. Because there is no evidence that the patentees sought to limit claims 23 and 24 to the specified means of tampering, the Court will give them the broader interpretation that is consistent with its construction of claim 1. *Cf.*

Am. Piledriving Equip., Inc. v. Geoquip, Inc., 637 F.3d 1324, 1333 (Fed. Cir. 2011) ("Where a claim term is used consistently throughout the claims, the usage of the term in one claim can often illuminate the meaning of the same term in other claims.") (internal quotation marks, citation, and alterations omitted). The Court therefore construes claims 23 and 24 to require "tampering that includes"—but is not limited to—the particular methods specified in those claims.

Finally, the Court rejects Purdue's request to specify water as an example of an aqueous liquid. As with claim 1, that construction is unnecessary.

* * *

For these reasons, the Court construes claims 23 and 24 of the '888 Patent to read as follows:

> 23. The controlled release oral dosage form of any of claims 2, 4, 5, 6 and 7, wherein the requisite viscosity is obtained when the dosage form is subjected to tampering that includes crushing and dissolution in the specified volume of aqueous liquid.
>
> 24. The controlled release oral dosage form of any of claims 2, 4, 5, 6 and 7, wherein the requisite viscosity is obtained when the dosage form is subjected to tampering that includes dissolution in the specified volume of aqueous liquid with heating greater than 45° C.

IV. CONSTRUCTION OF THE DISPUTED CLAIMS IN THE '060 PATENT

Plaintiffs allege that Teva's[4] ANDA infringes 17 of the '060 Patent's 34 claims: 2, 4, 5, 8, 9, 22, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, and 34. (Pls.' Opening Br. 19.) Of these, the parties only dispute the meaning of certain terms in dependent claim 9, which must be read in conjunction with independent claim 1. Independent claim 1 reads as follows:

> 1. An abuse-proofed, thermoformed dosage form comprising one or more active ingredients with abuse potential (A) optionally together with physiologically acceptable auxiliary substances (B), at least one synthetic or natural polymer (C), wherein the polymer (C) has a molecular weight of at least 0.5 million according to rheological

[4] Plaintiffs do not assert the '060 Patent against defendant Amneal.

> measurements, and optionally at least one wax (D), wherein the dosage form exhibits a breaking strength of at least 500 N.

'060 Patent at 21:6–14. Dependent claim 9 claims, in pertinent part:

> 9. A dosage form according to claim 1, which additionally comprises at least one of the following components a)-f):
>
> . . .
>
> (b) at least one viscosity-increasing agent, which, with the assistance of a necessary minimum quantity of an aqueous liquid, forms a gel with the extract obtained from the dosage form, which gel optionally remains visually distinguishable when introduced into a further quantity of an aqueous liquid,
>
> . . .

Id. at 21:37–38, 21:41–46. The parties dispute the meaning of four terms in claim 9, each of which the Court addresses below.

A. Construction of "viscosity-increasing agent (b)"

The bulk of the parties' dispute centers on the meaning of the following phrase in claim 9: "A dosage form according to claim 1, which additionally comprises . . . at least one viscosity-increasing agent." '060 Patent at 21:37–41. Specifically, the parties disagree whether viscosity-increasing agent (b), which is recited in claim 9, must be a different substance than hardening polymer (C), which imparts the breaking strength of 500 Newtons required by claim 1. *See* '060 Patent at 5:54–58, 21:6–14, 21:41. Plaintiffs contend that a single substance may serve both functions, so long as it confers the requisite characteristics of both hardness and viscosity. (Pls.' Opening Br. 22, 24.) Teva argues that hardening polymer (C) and viscosity-increasing agent (b) must be two separate and distinct substances; they further allege that the latter is limited to a particular list of substances contained in the specification. (Defs.' Opening Br. 16–19.)

1. Viscosity-increasing agent (b) and hardening polymer (C) must be different components

The Court begins with the language of claims 1 and 9. *See Innova/Pure Water, Inc.*, 381 F.3d at 1116. Claim 1 sets out a list of four elements that the dosage form comprises: one or more active ingredients with abuse

potential (A), optional auxiliary substances (B), at least one synthetic or natural polymer (C), and optionally at least one wax (D). '060 Patent at 21:6–14. Claim 9 then specifies several components, including viscosity-increasing agent (b), that the dosage form may "additionally comprise[]" as optional auxiliary substances (B). *Id.* at 6:35–40 (defining components a)-f) as auxiliary substances (B)), 21:37-51.

At the *Markman* hearing, the parties agreed that "additionally comprises" is not a term of art, and that a person of ordinary skill in the art would not construe the term differently from a lay person. (Hr'g Tr. 10, 20.) The Court agrees with Teva that the most natural reading of the phrase "additionally comprises" would require *something other* than hardening polymer (C). *See Phillips*, 415 F.3d at 1314 ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words."). Moreover, the fact that claim 1 lists hardening polymer (C) and auxiliary substances (B) as separate elements indicates that viscosity-increasing agent (b) cannot be the same substance as polymer (C). *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) ("Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention.") (internal quotation marks, citations, and alterations omitted). The structure of the claim language itself, then, indicates that two different substances must serve as hardening polymer (C) and viscosity-increasing agent (b).

The specification provides additional support for this construction. The following passages are probative:

- "Another option for preventing abuse of the dosage form according to the invention consists in adding at least one viscosity-increasing agent as a further abuse-preventing component (b) to the dosage form . . . ." '060 Patent at 8:19–22.
- "If component (b) is added to the dosage form according to the invention, one or more viscosity-increasing agents are used . . . . " *Id.* at 8:63–65.
- "[T]he dosage forms according to the invention may, in a preferred embodiment, contain further agents which complicate or prevent abuse as auxiliary substances (B)." *Id.* at 6:31–34.

"[C}ontain further agents," "adding at least one viscosity-increasing agent," and "component (b) is added" all signal the addition of a new, distinct substance—one that is not already present in the dosage form as hardening polymer (C). Plaintiffs counter that these phrases are broad enough to encompass the addition of a greater *amount* of polymer (C), rather than the addition of a new substance. (Pls.' Opening Br. 22–23.) But the language of the specification—which discusses "adding" "further agents" and "component[s]" rather than additional amounts of substances already present—provides little support for this interpretation.

Plaintiffs also argue that because the specification notes the viscous nature of certain substances that are suitable as polymer (C), it contemplates that those substances may also serve as viscosity-increasing agent (b). The specification states: "Thermoplastic polyalkylene oxides, such as polyethylene oxides . . . are very particularly preferred [as polymer (C)]. These polymers have a viscosity at 25° C. of 4500 to 17600 cP . . . ." '060 Patent at 5:65–6:3. But the specification's passing reference to the viscosity of certain polymers does not eviscerate the importance of the numerous other statements that focus on the addition of a new substance. *See Takeda Pharm. Co. Ltd.*, 743 F.3d at 1365 (concluding that the use of the phrase "about 400 μm" three times in the specification did not defeat stronger evidence that particle size could not exceed 400 μm). For example, almost immediately after the specification describes the viscosity of thermoplastic polyalkylene oxides, it goes on to state that the dosage form may "contain further agents which complicate or prevent abuse as auxiliary substances (B)." '060 Patent at 6:33–34. Nowhere in that passage does the specification even hint that the viscous quality of thermoplastic polyalkylene oxides makes them suitable as auxiliary substances (B). Rather, the use of the phrase "contain further agents" indicates that something *besides* polymer (C) is required, regardless of that polymer's own viscosity.

Plaintiffs also point to claim 24, which provides that hardening polymer (C) may serve as a controlled release matrix material in addition to conferring the 500 Newton breaking strength required by claim 1. '060 Patent at 16:44–47, 22:65–67. According to plaintiffs, this demonstrates that the patentees intended polymer (C) to serve multiple functions, including that of viscosity-increasing agent (b). Plaintiffs undercut their own position. The fact that the patentees expressly stated that polymer (C)

could also serve as a controlled release matrix material shows that they knew exactly how to establish dual functionality when they wanted to. *See Takeda Pharm. Co. Ltd.*, 743 F.3d at 1365 (rejecting a construction that would allow deviation in particle size in part because "the inventors knew how to express ambiguity in claim language when they so desired"). Yet the patentees never stated that polymer (C) could also serve as viscosity-increasing agent (b) or any of the other auxiliary substances (B). The patentees' express disclosure of the dual functionality of polymer (C) in the context of controlled release matrix materials does not permit the Court to extend it to an entirely different situation, given the many statements in the specification that evince the patentees' intent to require the addition of a distinct substance as agent (b).

The six examples disclosed in the specification lend further support to a construction that requires the addition of a new substance. Examples 1, 2, and 3 describe the formation of a tablet consisting of an active ingredient and PEO, one of the substances the specification identifies as a suitable hardening polymer. '060 Patent at Examples 1–3, 5:54–60. These examples disclose the tablets' breaking strength, but not their viscosity. '060 Patent at Examples 1–3. Examples 4, 5, and 6, by contrast, feature tablets consisting of an active ingredient, PEO, and xanthan, which the specification lists as a viscosity-increasing agent. *Id.* at Examples 4–6, 8:63–9:15. Each of these examples discloses both the tablets' breaking strength *and* their viscosity when combined with water. *Id.* at Examples 4–6. By discussing viscosity only when an additional, non-polymer (C) component was added, the examples further demonstrate that hardening polymer (C) cannot serve as viscosity-increasing agent (b).

Plaintiffs make a futile attempt to downplay the significance of the examples, arguing that xanthan was added merely to enable the tablets in Examples 3–5 to meet the optional "visually distinguishable" test of claim 9.[5] (Pls.' Opening Br. 22–23.) They explain that Example 1's tablet contains 200 mg of PEO and no xanthan, while Example 4's tablet features an

[5] As discussed more fully below, claim 9 features a "gelling test" that requires the formation of a gel when the viscosity-increasing agent and the "extract obtained from the dosage form" are combined with an aqueous liquid. '060 Patent at 21:41–44. It further provides that the gel "optionally remains visually distinguishable when introduced into a further quantity of an aqueous liquid." *Id.* at 21:44–46.

identical formulation aside from the replacement of 20 mg of PEO with 20 mg of xanthan. (Pls.' Opening Br. 22.) Examples 3 and 5 exhibit a similar pattern. '060 Patent at Examples 3, 5. This "substitution" of xanthan for PEO, according to plaintiffs, allowed Examples 4 and 5 to produce a gel that remained visually distinguishable when introduced into a quantity of liquid. (Pls.' Opening Br. 22–23.) Therefore, plaintiffs argue, "either an excess of polymer (C) or the addition of xanthan can be used in the invention." (*Id.* 23.) Importantly, plaintiffs do not allege that Examples 1–3, which utilized only polymer (C), produced a dosage form viscous enough to form the gel required by claim 9. Nor can this fact be inferred from the examples themselves. Consequently, because there is no evidence that the PEO in Examples 1–3 actually functioned as viscosity-increasing agent (b), plaintiffs' argument is meritless.

In sum, the specification treats polymer (C) and viscosity-increasing agent (b) as distinct components in every instance it discusses them. *See Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1144 (Fed. Cir. 2005) (interpreting the claim term "board" to mean "wood decking material cut from a log" because the specification consistently described it that way); *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1381–82 (Fed. Cir. 2005) (concluding, in part "based upon the teachings of the specification," that the claim term "fiberfill batting material" did not include natural fibers). Accordingly, the Court construes the disputed term in claim 9 to mean: "A dosage form according to claim 1, which additionally comprises at least one of the following components a)-f): . . . (b) at least one viscosity-increasing agent different from the synthetic or natural polymer (C) of claim 1 . . . ."

2. Viscosity-increasing agent (b) is not limited to the list of substances in the specification

Having concluded that viscosity-increasing agent (b) cannot be the same substance as hardening polymer (C), the Court now considers Teva's argument that agent (b) is limited to a list of specific substances set out in the specification. (Defs.' Opening Br. 18–19.) That passage provides:

> If component (b) is added to the dosage form according to the invention, one or more viscosity-increasing agents are used which are selected from the group consisting of microcrystalline cellulose with 11 wt. % carboxymethylcellulose sodium (Avicel®

> RC 591), carboxymethylcellulose sodium (Blanose®, CMC-Na C300P®, Frimulsion BLC-5®, Tylose C300 P®), polyacrylic acid (Carbopol® 980 NF, Carbopol® 981), locust bean flour Cesagum® LA-200, Cesagum® LID/150, Cesagum® LN-l), pectins such as citrus pectin (Cesapectin® HM Medium Rapid Set), apple pectin, pectin from lemon peel, waxy maize starch (C*Gel 04201®), sodium alginate (Frimulsion ALG (E40l)®), guar flour (Frimulsion BM®, Polygum 26/1-75®), iota carrageen (Frimulsion D021®), karaya gum, gellan gum (Kelcogel F®, Kelcogel LT100®), galactomannan (Meyprogat l50®), tara bean flour (Polygum 43/10), propylene glycol alginate (Protanal-Ester SD-LB®), sodium hyaluronate, tragacanth, tara gum (Vidogum SP 200®), fermented polysaccharide welan gum (K1A96), xanthan gum (Xantural 180®).

'060 Patent at 8:63–9:14. Teva argues that because the specification utilizes a so-called "Markush group" formulation—"selected from the group consisting of"—it limits viscosity-increasing agent (b) of claim 9 to a list of specified alternatives. (Defs.' Opening Br. 18; Hr'g Tr. 24–25.)

It is black letter law that courts may not import limitations from the specification into the claims unless the claim language or the specification makes clear that the invention includes the limitation. *Phillips*, 415 F.3d at 1320; *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc*, 242 F.3d 1337, 1340 (Fed. Cir. 2001). The structure and language of the '060 Patent's claims indicate that claim 9 is not so limited. Claim 9 requires only that the viscosity-increasing agent, if used, "forms a gel" under certain specified conditions. '060 Patent at 21:41–46. Claim 15, which depends from claim 9, is narrower: it requires that the viscosity-increasing agent be selected from the same list of compounds set out in the specification.[6] *Id.* at 22:15–33. If the patentees really intended claim 9 to contain the same limitations as claim 15, they would have had little reason to include claim 15 in the patent. *See Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007) ("[T]he language of the claims and [the doctrine of] claim differentiation imply that the "pharmaceutically acceptable polymer" term

[6] Upon close inspection, a few of the trade names of the substances in claim 15 contain slight differences from those listed in the specification. No party has addressed this issue, which appears to be simply the result of typographical errors.

in claim 1 . . . encompasses more compounds than those listed in claim 3."); *see also Acumed LLC*, 483 F.3d at 806 (stating the presumption that "independent claims are presumed to have broader scope than their dependents").

Moreover, the fact that the patentees included a Markush group in the specification, '060 Patent at 8:63–9:14, provides little support for Teva's argument that claim 9 is limited to the substances set out in that group. The Federal Circuit, in a case very similar to this one, warned that "[t]he term "Markush group" does not have any meaning within the context of a written description of a patent" and cannot be used to "limit [the court's] construction to the compounds listed in the written description." *Abbott Labs.*, 473 F.3d at 1210. Teva responds that the patentees acted as their own lexicographers by defining "viscosity-increasing agent" to mean the enumerated list of substances. (Defs.' Opening Br. 18.) The specification, however, is devoid of any language "clearly express[ing] an intent" to redefine the term "viscosity-increasing agent" to encompass only the closed list of compounds. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal quotation marks and citations omitted). When the patentees defined other terms in the '060 Patent, they used express language. '060 Patent at 7:53–54 ("A dosage unit is taken to mean . . . ."), 8:28–29 ("For the purposes of the present invention visually distinguishable means . . . ."), 8:41–42 ("If the gel remains visually distinguishable, this means that . . . ."). The lack of such language with respect to the disputed claim term indicates that the patentees were not acting as their own lexicographers when they included the Markush group in the specification.

Teva has not pointed to any other evidence supporting its proposed construction that claim 9's "viscosity-increasing agent" is limited to the Markush group's list of substances, and the Court cannot find any. In fact, the specification suggests that agent (b) of claim 9 is broader than the list of specified compounds. It recites a test for "verify[ing] whether a viscosity-increasing agent is suitable as component (b)." '060 Patent at 8:55–62. If the patentees intended to limit agent (b) to the specific compounds contained in the Markush group, it is difficult to understand why they would have found it necessary to devise this test.

Accordingly, the Court concludes that viscosity-increasing agent (b), as it appears in claim 9, is not limited to the list of specific substances set out in the specification at 8:63–9:14.

B. "A necessary minimum quantity of an aqueous liquid" means "an aqueous liquid in a necessary minimum quantity"

Claim 9 provides that a gel forms when the viscosity-increasing agent is combined with the extract obtained from the dosage form and "a necessary minimum quantity of an aqueous liquid." '060 Patent at 21:41–46. The Court will refer to this requirement as the "gelling test." Teva contends that "a necessary minimum quantity of an aqueous liquid" is indefinite, an argument the Court again declines to consider before trial. (Defs.' Opening Br. 20.) Plaintiffs, on the other hand, urge the Court to construe the disputed phrase to mean "10 ml of water at a temperature of 25° C." (Pls.' Opening Br. 24.)

The language of claim 9 itself offers no guidance on the meaning of "a necessary minimum quantity of an aqueous liquid," and the specification includes no explicit definition. Plaintiffs urge, however, that the meaning of the phrase is contained within a test the patentees described in the specification for verifying the suitability of a viscosity-increasing agent for use in the dosage form. That test, which the Court will refer to as the "specification test," provides:

> [T]he active ingredient is mixed with the viscosity-increasing agent and suspended in 10 ml of water at a temperature of 25° C. If this results in the formation of a gel which fulfills the above-stated conditions, the corresponding viscosity-increasing agent is suitable for preventing or averting abuse of the dosage forms according to the invention.

'060 Patent at 8:55–62.

Although using the language of the specification test to define "a necessary minimum quantity of an aqueous liquid" carries some initial appeal, it ultimately fails because the test, upon closer examination, lacks the necessary connection to claim 9. Claim 9's gelling test applies to the dosage form *as a whole*. '060 Patent at 21:37–38, 21:41–44. It states that a gel must form from the combination of the viscosity-increasing agent, a necessary minimum quantity of an aqueous liquid, and the extract obtained from the dosage form. '060

Patent at 21:41–44. The specification test, however, is designed to assess whether a particular *viscosity-increasing agent* is suitable for use in the invention. *Id.* at 8:55–57. Moreover, that test utilizes different inputs, calling for the "active ingredient" instead of the "extract obtained from the dosage form." *Compare id.* at 8:57–59, *with id.* at 21:41–44. This difference is important: the dosage form of claim 9 consists—at a minimum—of an active ingredient, a synthetic or natural polymer (C), and a viscosity-increasing agent. *Id.* at 21:5–14, 21:37–41. The specification test, however, excludes polymer (C), a substance that may influence gel formation. *See* '060 Patent at 6:2–9 (describing the high viscosity of such polymers), 8:55–59. The fact that the two tests feature different inputs that could affect the outcome indicates that they do not describe the same subject matter. Consequently, it cannot be said that a person of ordinary skill in the art would understand "a necessary minimum quantity of an aqueous liquid" in claim 9 to refer to "10 ml of water at a temperature of 25° C."

Extrinsic evidence further confirms that plaintiffs' proposed construction is incorrect. Heinrich Kugelmann, one of the inventors of the '060 Patent, was asked at his deposition whether he knew what would constitute the minimum quantity of aqueous liquid required by claim 9. He responded:

> A: So it depends, really, on the volume of the medication formulation to be examined, meaning that a smaller volume or entity of medication would require a smaller amount of aqueous liquid as opposed to a larger medication amount that would require a larger amount of aqueous liquid.
>
> Q: Does it depend on anything else besides the volume of the medication formulation?
>
> MS. SOMMERS: Objection.
>
> A: No, I don't know. I don't know. That was just an example on which, of a factor upon which it may depend.

(Ex. A. to Decl. of Steven J. Bernstein dated Feb. 14, 2014, at 81:10–21.) The fact that an inventor of the '060 Patent did not identify 10 ml of water at a temperature of 25°C as the "necessary minimum quantity of an aqueous liquid" provides yet another element to support the Court's conclusion

that plaintiffs' proposed construction is erroneous. *See Phillips*, 415 F.3d at 1317, 1324 (authorizing courts to consider inventor testimony so long it does not contradict the intrinsic evidence).

Finally, plaintiffs attempt to buttress their proposed interpretation by contending that it is consistent with the Court's prior construction of U.S. Patent No. 7,776,314 ("'314 Patent"), which recites a gelling requirement similar to that contained in the '060 Patent's claim 9. *See* '314 Patent at 11:65–12:31; (Pls.' Opening Br. 25.) Their argument misses the mark. Unlike the '060 Patent, the '314 Patent's requirement of "10 ml of water at 25° C." appears in the very language of its *claims*. '314 Patent at 12:25–28 (stating that the dosage form must comprise "at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel"). Moreover, the Court never construed the phrase "a necessary minimum quantity of an aqueous liquid" because that language was not part of the '314 Patent's claims. The fact that the '314 Patent specified the amount, type, and temperature of aqueous liquid required for its gelling test does not give the Court license to import those limitations into the '060 Patent.

In short, there is simply nothing in the intrinsic or extrinsic evidence that can bridge the large gap between the claim language and plaintiffs' proposed construction, which dramatically narrows "necessary minimum" to "10 ml" and "aqueous liquid" to "water," while imposing a temperature requirement of which the claim is completely devoid of reference. The Court therefore turns to the remainder of the specification for guidance on the meaning of the disputed phrase.

Although "a necessary minimum quantity of an aqueous liquid" appears four times in the '060 Patent's specification, the relevant passages merely repeat the language of claim 9 without providing any direction on its meaning. *See* '060 Patent at 6:43–46, 8:19–24, 8:28–31, 9:23–27. The three examples that discuss gelling are similarly unhelpful. Examples 4, 5, and 6 report that a gel forms when small pieces of the dosage form "are combined with water." '060 Patent at Examples 4–6. The examples do not disclose the quantity or temperature of the water. *Id.* The only guidance the examples provide, then, is that water is one example of an aqueous liquid, which the parties obviously do not dispute.

The intrinsic and extrinsic evidence, in sum, do not disclose a meaning of "a necessary minimum quantity of an aqueous liquid" beyond the words themselves. The Court therefore construes "a necessary minimum quantity of an aqueous liquid" to mean "an aqueous liquid in a necessary minimum quantity." *Cf. Alcon Research, Ltd.*, 2011 WL 3901878, at *17 (evaluating the parties' proposed constructions of "therapeutically effective amount," but declining to provide a construction that went beyond the words of the patent prior to trial). Whether this claim language "reasonably apprise[s] those skilled in the art of the scope of the invention" is a matter to be explored at trial. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) (defining indefiniteness).

C. "Forms a gel with the extract obtained from the dosage form" means "forms a gel with the extract obtained from the dosage form, which gel is difficult or impossible to pass through a needle or inject"

The Court's consideration of claim 9's gelling test is not yet complete. Teva asks the Court to construe the phrase "forms a gel with the extract obtained from the dosage form." (Defs.' Opening Br. 22); *see also* '060 Patent at 21:43–44. It argues that the phrase is indefinite because the term "gel" is "rather amorphous and undefined." (Defs.' Opening Br. 22.) Again, the Court declines to rule on the claim's indefiniteness prior to trial.

Teva is correct that the patentees did not provide an express definition of "gel." And unlike the '888 Patent, the '060 Patent does not specify a quantitative measurement of viscosity. Nonetheless, the specification does offer guidance on the characteristics of the gel that claim 9 requires. It states that the claimed gel is "virtually impossible to administer safely," '060 Patent at 8:25, and that the "increased viscosity of the extract makes it more difficult or even impossible for it to be passed through a needle or injected," *id.* at 8:39–41. Examples 4, 5, and 6 also describe the difficulty of injecting the gel. They report that when pieces of the dosage form were combined with water, a "highly viscous gel is formed" and "[o]nly with great difficulty could the gel be pressed through a 0.9 mm injection cannula." '060 Patent at Examples 4–6. The examples in the specification make clear, then, that the gel of claim 9 must be difficult or impossible to pass through a needle or inject.

Plaintiffs ask the Court to construe the disputed phrase to mean "an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel." (Pls.' Opening Br. 25–26.) The Court has already considered and rejected plaintiffs' contention that the gelling test of claim 9 requires 10 ml of water at a temperature of 25° C. In addition, plaintiffs do not explain why the Court should employ the term "aqueous extract," which appears nowhere in the patent. Both the claims and the specification refer to "the extract obtained from the dosage form," and the Court cannot ascertain any reason to detach "extract" from "dosage form" and append it to "aqueous," as plaintiffs' construction would have it.[7]

For these reasons, the Court interprets "forms a gel with the extract obtained from the dosage form" to mean "forms a gel with the extract obtained from the dosage form, which gel is difficult or impossible to pass through a needle or inject."

D. The optional "visually distinguishable" claim term requires no construction

Teva has submitted the following phrase from claim 9 for construction: "which gel optionally remains visually distinguishable when introduced into a further quantity of an aqueous liquid." (Defs.' Opening Br. 23–24); *see also* '060 Patent at 21:44–46. The parties agree that this claim term is optional. (Hr'g Tr. 15–16.) Optional terms can always be omitted and do not narrow the scope of a claim. *In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006); MPEP § 2111.04 (9th ed., Mar. 2014). Both parties agree that construction of the "visually distinguishable" phrase is not necessary, but Teva nonetheless urges the Court to adopt a construction in order to "complete the record." (Hr'g Tr. 16.) Given that construction of this term would have no impact on the litigation, the Court declines to do so in the interest of judicial restraint. *See Vivid Techs., Inc.*, 200 F.3d at 803 (noting that claim terms need only be construed "to the extent necessary to resolve the controversy").

* * *

For these reasons, the Court construes claim 9 to read as follows:

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[7] At the *Markman* hearing, Teva argued for the first time that claim 9 is invalid because the term "extract obtained from the dosage form" lacks an antecedent basis. (Hr'g Tr. 40.) The Court defers judgment on this issue until trial.

> 9. A dosage form according to claim 1, which additionally comprises at least one of the following components a)-f):
>
> . . .
>
> (b) at least one viscosity-increasing agent different from the synthetic or natural polymer (C) of claim 1, which, with the assistance of an aqueous liquid in a necessary minimum quantity, forms a gel with the extract obtained from the dosage form, which gel is difficult or impossible to pass through a needle or inject, and which optionally remains visually distinguishable when introduced into a further quantity of an aqueous liquid,
>
> . . .

V. CONCLUSION

The '888 and '060 patents will now proceed to trial. On the basis of the claim construction set forth above, the Court will determine whether defendants' ANDAs infringe plaintiffs' patents and whether these patents are valid.

Dated: New York, New York
May 27, 2014

SO ORDERED:

Sidney H. Stein, U.S.D.J.